IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

EXPRESS SCRIPTS, INC. *Plaintiff*, v. THE FEDERAL TRADE COMMISSION, and LINA M. KHAN, in her official capacity as Chair of the Federal Trade Commission, *Defendants*.	Case No. 4:24-cv-1263-JSD

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

UNITED STATES CONSTITUTION

STATUTES

OTHER AUTHORITIES

INTRODUCTION

This action concerns an Interim Staff Report containing information that the Federal Trade Commission ("FTC") has obtained to date about the pharmacy-benefit manager ("PBM") industry. While the Commission's study of the industry is ongoing, a bipartisan majority of Commissioners voted to allow Commission Staff to release the Interim Report to inform Congress and the public of their initial findings. These initial findings did not purport to have legal effect or impose legal obligations, and the Interim Report does not compel any PBM to take or cease any action. Indeed, as befits an *interim* report, the Commission Staff's conclusions are carefully qualified—for example, the Interim Report explains how, based on materials obtained thus far in the study, PBMs "*may* be profiting by inflating drug costs" and "*sometimes* negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives." Nonetheless, Plaintiff Express Scripts, Inc. ("ESI"), one of the largest PBMs nationwide, brings this action to force the Commission and its Chair to retract the report. To do so, ESI asserts a grab-bag of challenges under the Administrative Procedure Act ("APA"), Missouri common law, and the United States Constitution. For both procedural and substantive reasons, these claims lack merit.

First, ESI's APA claims, Counts III and IV, are not properly before this Court because Congress authorized the Commission to release information when doing so is "in the public interest." The only appellate courts to have addressed the issue both held that this grant of authority lacks any judicially enforceable standard, and therefore commits the decision to release information to the Commission's discretion. Independently, ESI cannot assert an APA claim because the release of the Interim Report is not final agency action—the Interim Report does not mark the consummation of any Commission decision-making process, and it does not carry any independent legal effect.

Second, ESI's state-law defamation claim, Count I, should be dismissed for lack of subject-matter jurisdiction and for failure to state a claim upon which relief can be granted. Congress has not

waived sovereign immunity such that federal officials, exercising discretion afforded by federal law, may be subject to state-law defamation claims for declaratory and injunctive relief. The Supremacy Clause also precludes the use of state law to regulate federal officials' exercise of their statutorily afforded discretion, and therefore independently forecloses relief. In any event, even if ESI could overcome these threshold obstacles, ESI would still fail to state a defamation claim under Missouri law because ESI mischaracterizes the Interim report's conclusions and fails to show that those qualified conclusions—or the Commission's summary in an accompanying press release—are false.

Third, ESI's due process claim, Count II, fails to state a claim. To invoke the protections of the Due Process Clause, ESI must show that the mere release of the Interim Report deprived it of life, liberty, or property. ESI fails to make any such cognizable allegations. Moreover, ESI fails to allege that the Commission and Chair's actions and statements amount to the type of conflict of interest (or even bias) necessary to state a due process claim.

Finally, ESI's Article II challenge to the Commissioners' statutory removal protection, Count V, fails to state a claim. In *Humphrey's Executor v. United States*, 295 U.S. 602 (1935), the Supreme Court upheld the removal provision that ESI challenges here. This Court may not disregard that precedent unless the Supreme Court overrules it. Independently, ESI fails to allege that the challenged removal protections caused ESI any harm. Supreme Court precedent is clear on this point, too: absent allegations of prejudice from the asserted constitutional infirmity, ESI has not stated a claim.

For these reasons, as detailed below, this Court should grant Defendants' motion to dismiss.

BACKGROUND

A. The Commission's Statutory Authorizations

Section 6(b) of the FTC Act grants the Commission authority to "require, by general or special orders," that "persons, partnerships, and corporations, engaged in or whose business affects commerce," "to file with the Commission in any such form as the Commission may prescribe . . .

reports or answers in writing to specific questions." 15 U.S.C. § 46(b). Answers must "be made under oath, or otherwise, as the Commission may prescribe, and shall be filed with the Commission within such reasonable period as the Commission may prescribe." *Id.*

Section 6(f) of the FTC Act governs the Commission's release of that information. It authorizes the Commission:

> To make public from time to time such portions of the information obtained by it hereunder as are in the public interest; and to make annual and special reports to the Congress and to submit therewith recommendations for additional legislation; and to provide for the publication of its reports and decisions in such form and manner as may be best adapted for public information and use.

15 U.S.C. § 46(f).[1]

B. The Commission's PBM Study

On June 7, 2022, the Commission announced that it had unanimously voted to authorize under Section 6(b) a study of the six largest PBMs in the United States, including ESI, to "scrutinize the impact of vertically integrated pharmacy benefit managers on the access and affordability of prescription drugs." *See* FTC, *FTC Launches Inquiry Into Prescription Drug Middleman Industry* (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.[2] Chair Khan emphasized that the Commission had "received complaints about PBM practices from patients and professionals across the healthcare system," and that the Commission's "forthcoming PBM inquiry will examine several of the most common complaints about PBMs and will seek to assist policymakers in determining whether Americans would benefit from reforms to this critical industry." *See* Chair Lina Khan, *Statement Regarding 6(b) Study of*

[1] Trade secrets and other "commercial or financial information . . . which is privileged or confidential" may not be released except to officers and employees of state, federal, and foreign law enforcement agencies under specified conditions. 15 U.S.C. § 46(f). For this reason, the Interim Report anonymizes and aggregates information that the PBM respondents provided to Commission Staff.

[2] On a motion to dismiss, this Court may consider "matters of public and administrative record referenced in the complaint," *Owen v. Gen. Motors Corp.*, 533 F.3d 913, 918 (8th Cir. 2008), including the Interim Report, the accompanying press release, and related Commission statements.

Pharmacy Benefit Managers (June 8, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement-Khan-6b-Study-Pharmacy-Benefit-Managers.pdf. In a concurring statement, two Commissioners acknowledged that the Commission had previously assessed the PBM industry, explaining that "markets evolve, and so further study is warranted." Commissioners Phillips and Wilson, *Concurring Statement Regarding Orders to Study Contracting Practices of Pharmacy Benefit Managers* (June 6, 2022) https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PhillipsWilsonPBMStatement.pdf.

On July 20, 2023, the Commission announced that it had unanimously "voted to issue a statement cautioning against reliance on" the Commission's "prior advocacy statements and studies related to" PBMs "that no longer reflect current market realities." *See* FTC, *FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy* (July 20, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy. The Commission warned that, because it "is currently engaged in a major study of the PBM industry[] undertaken . . . due to the . . . substantial changes have taken place over the last two decades," "reliance on [its] conclusions in certain prior statements and reports may be misplaced." FTC, *Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities* (July 20, 2023) ("Withdrawal Statement") at 1, https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.

C. The Staff Interim Report

A bipartisan majority of Commissioners voted 4-1 to allow Commission Staff to issue the Interim Report on July 9, 2024. FTC, *FTC Releases Interim Staff Report on Prescription Drug Middlemen* (July 9, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen. The Interim Report was based on Staff review of "more than 1,200 public comments"; "initial submissions of internal documents and data from PBM

respondents and their affiliates"; "interview[s with] various industry experts and participants"; and "other public data and information." FTC, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report* (July 2024) ("Interim Report") at 4, https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf. The Interim Report "provides . . . key insights supported by the documents and data obtained to date," including:

- "The market for [PBM] services has become highly concentrated, and the largest PBMs are now also vertically integrated with the nation's largest health insurers and specialty and retail pharmacies."
- "As a result of this high degree of consolidation and vertical integration, the leading PBMs *can* now exercise significant power over Americans' access to drugs and the prices they pay."
- "Vertically integrated PBMs *may* have the ability and incentive to prefer their own affiliated businesses, which in turn *can* disadvantage unaffiliated pharmacies and increase prescription drug costs."
- "Evidence suggests that increased concentration *may* give the leading PBMs the leverage to enter into complex and opaque contractual relationships that *may* disadvantage smaller, unaffiliated pharmacies and the patients they serve."
- "PBMs and brand drug manufacturers *sometimes* negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives."

Id. at 2-4 (emphases added). As the emphasized language demonstrates, the Interim Report qualified its conclusions, highlighting repeatedly that its determinations to date were only that PBMs "may" and "sometimes" exercise control over drug pricing. And the Interim Report further underscored that its findings were based only on the review that Commission Staff had conducted to date. *Id.* at 2 ("The failure of certain respondents to timely produce data and documents has hindered the ability of the Commission . . . ."); *id.* at 4 ("We remain committed to providing timely updates as we receive and review additional information.").

The Interim Report also makes clear the basis for its preliminary conclusions. For instance, the Interim Report describes how PBMs "may be profiting by inflating drug costs." *Id.* at 1. It "highlight[s] examples of [PBM-]affiliated pharmacies receiving significantly higher reimbursement rates than those paid to unaffiliated pharmacies for two case study drugs . . . [and] retain[ing] levels of

dispensing revenue well above estimated drug acquisition costs, resulting in nearly $1.6 billion of additional revenue on just two cancer drugs in under three years." *Id.* at 3. However, the Interim Report is clear that its conclusions are limited in scope—it repeatedly highlights that Commission Staff's findings are tied to their assessment of "two case study drugs." *See, e.g.*, *id.* at 40 ("[O]ur findings are necessarily limited to the two case study drugs . . .").

LEGAL STANDARDS

To survive a motion to dismiss for failure to state a claim under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Cox v. Mortg. Elec. Registration Sys., Inc.*, 685 F.3d 663, 668 (8th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "A claim has facial plausibility when the plaintiff [has pleaded] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Iqbal*, 556 U.S. at 678). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Under Rule 12(b)(1), a plaintiff bears the burden of establishing that the court has subject-matter jurisdiction over her claims. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998).

ARGUMENT

I. ESI's APA claims (Counts III and IV) are not properly before this Court.

A. The Commission's ability to release information pursuant to 15 U.S.C. § 46(f) is committed to agency discretion by law.

While the APA creates a presumption of judicial review, *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986), "[t]his is 'just' a presumption . . . and under [5 U.S.C.] § 701(a)(2) agency action is not subject to judicial review 'to the extent that' such action 'is committed to agency discretion by law,'" *Lincoln v. Vigil*, 508 U.S. 182, 190-91 (1993). To determine whether Congress committed an action to agency discretion by law, courts assess whether "the statute is drawn so that

a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985); *see also Tamenut v. Mukasey*, 521 F.3d 1000, 1004 (8th Cir. 2008) (en banc) ("The absence of any statutory factors to guide the agency's decision-making process, in combination with the open-ended nature of the inquiry, generally supports the conclusion that the 'agency action is committed to agency discretion by law.'").

Section 46(f) provides no such meaningful standard. Unless the released information involves trade secrets or other confidential information, which ESI does not allege to be at issue here, that provision states that "the Commission shall also have power" "[t]o make public from time to time such portions of the information obtained by it hereunder as are in the public interest." 15 U.S.C. § 46(f). Every part of this authorization confers broad discretion—the Commission has the power to release any information on any schedule it sees fit, although it is never required to do so, so long as the release is in the public interest and complies with confidentiality requirements. Accordingly, the only two appellate courts to address Section 46(f) have held that it commits the release of information to agency discretion by law. *Fleming v. FTC*, 670 F.2d 311, 317 (D.C. Cir. 1982) ("In limiting the scope of judicial review to whether the Commission has complied with the statutory prerequisites of §§ 6(f) and 21(b)(6), we acknowledge the discretionary authority vested in the Commission by Congress through these statutes. We conclude that the Commission's disclosure was entirely within its discretion as long as the statutory prerequisites were met."); *Jaymar-Ruby, Inc. v. FTC*, 651 F.2d 506, 512 (7th Cir. 1981) ("[W]e hold that Commission decisions to release materials pursuant to § 6(f), as amended, are discretionary in nature and exempt from judicial review so long as the two statutory prerequisites are satisfied.").

To be sure, both of those cases involved the release of confidential information to state law enforcement agencies upon certification that the information would be maintained in confidence and used for law enforcement purposes. But the overarching standard for release of confidential

information to law enforcement officials—"as are in the public interest," 15 U.S.C. § 46(f)—is the same as for release of nonconfidential information to the public, and both courts determined that statutory language did not provide a meaningful standard for assessing the agency's exercise of discretion. Indeed, the grant of discretion to release to the public the nonconfidential and anonymized information at issue here is even broader than the grant of discretion to release the confidential information assessed in *Fleming*, 670 F.2d 311, and *Jaymar-Ruby*, 651 F.2d 506, because the information here is not subject to the statutory requirement that the agency receive a certification from an officer of the law enforcement agency. *See* 15 U.S.C. § 46(f). Accordingly, this Court should join the only two appellate courts to have addressed Section 46(f) and hold that this provision commits the release of information, where statutory prerequisites are met, to the Commission's discretion by law.[3]

Indeed, that outcome would be correct even absent *Fleming* and *Jaymar-Ruby*. The Supreme Court has held that actions are committed to agency discretion by law where the standard for the challenged action is "necessary or advisable in the interests of the United States." *Webster v. Doe*, 486 U.S. 592, 600 (1988). And multiple courts of appeals have held that other statutes that direct an agency to take or withhold action "in the public interest," like 15 U.S.C. § 46(f), commit those actions to agency discretion by law. *See Forsyth Cnty. v. U.S. Army Corps of Eng'rs*, 633 F.3d 1032, 1041 (11th Cir. 2011) (holding that statute directing Secretary to "award leases 'for such periods, and upon such terms and for such purposes as he may deem reasonable in the public interest'" committed that decision to agency discretion by law); *Claybrook v. Slater*, 111 F.3d 904, 908 (D.C. Cir. 1997) ("Adjourning a meeting

[3] Courts in other contexts have also recognized that Section 46(f) grants broad discretion to the Commission. *See FTC v. Freecom Commc'ns, Inc.*, 966 F. Supp. 1066, 1067 (D. Utah 1997) ("Congress . . . specifically authorized the FTC to make news releases under 15 U.S.C. § 46(f) . . . The decision to make such a release is discretionary with the FTC and not generally subject to judicial review."); *Interco Inc. v. FTC*, 478 F. Supp. 103, 106 (D.D.C. 1979) ("Section 6(f) of the Federal Trade Commission Act . . . grants the Commission wide discretion to release documents except for trade secrets and lists of customers.").

in 'the public interest' is the kind of decision that resists judicial review."). Accordingly, insofar as "in the public interest" expresses a statutory purpose, "it is only a hortatory purpose, not a specific one" as necessary to provide a meaningful standard for assessing the Commission's release of information. *Target Training Int'l, Ltd. v. Lee*, 1 F. Supp. 3d 927, 947 (N.D. Iowa 2014) (holding authorization to act "when justice requires" committed action to agency discretion by law). Thus, this Court should dismiss ESI's APA claims. *Id.*

B. ESI does not challenge any final agency action.

The Administrative Procedure Act "provides for judicial review of 'final agency action for which there is no other adequate remedy in a court.'" *Sackett v. EPA*, 566 U.S. 120, 125 (2012) (quoting 5 U.S.C. § 704). "Two conditions must be satisfied for an agency action to be 'final': First, the action must mark the 'consummation of the agency's decisionmaking process.'" *Sisseton-Wahpeton Oyate of Lake Traverse Rsrv. v. U.S. Corps of Eng'rs*, 888 F.3d 906, 915 (8th Cir. 2018) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)). "Second, 'the action must be one by which rights or obligations have been determined, or from which legal consequences will flow.'" *Id.* (quoting *Bennett*, 520 U.S. at 178). The Interim Report satisfies neither condition, requiring dismissal.[4]

First, the Interim Report is just that—an *interim* report. The Interim Report states that it "is part of an ongoing study," and that it encompasses only "preliminary findings . . . supported by the documents and data obtained to date." Interim Report at 1-2; *see also, e.g.*, *id.* at 4 ("We remain committed to providing timely updates as we receive and review additional information."); *id.* at 53 ("[O]ur initial review of documents received thus far reveals that . . ."). Such "preliminary opinion[s]"

[4] There exists inconsistent authority within the Eighth Circuit as to whether the APA's final-agency-action requirement is jurisdictional. *Compare, e.g.*, *Batsche v. Price*, 875 F.3d 1176, 1177 (8th Cir. 2017) (jurisdictional); *Sierra Club v. U.S. Army Corps of Eng'rs*, 446 F.3d 808, 813-16 (8th Cir. 2006) (jurisdictional) *with Iowa League of Cities v. EPA*, 711 F.3d 844, 863 n.12 (8th Cir. 2013) (not jurisdictional). This distinction is not relevant here: under either Rule 12(b)(1) or Rule 12(b)(6), ESI's APA claims should be dismissed for lack of final agency action.

do not "constitute final agency action" because they remain subject to revision. *Mo. Pac. Emps.' Hosp. Ass'n v. Donovan*, 576 F. Supp. 208, 211 (E.D. Mo. 1983), *aff'd*, 745 F.2d 1174 (8th Cir. 1984); *see also Franklin v. Massachusetts*, 505 U.S. 788, 798 (1992) (explaining that an agency report that "serves more like a tentative recommendation than a final and binding determination" is not a final agency action).

Moreover, the Interim Report "explicitly and repeatedly states that it expresses the views of 'staff,'" which further supports the conclusion that the Interim Report was "informal" because it was only the determination "'of a subordinate official,' and not that of any individual Commissioner or of the full Commission." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1268 (D.C. Cir. 2018). Indeed, the Concurring Statement of Commissioner Ferguson emphasizes that the Interim Report "is not a statement or report of the Commission," but "instead the staff's report to the Commission about how it understands our complex healthcare markets." Commissioner Ferguson, FTC, *Concurring Statement Regarding the Pharmacy Benefit Managers Interim Staff Report*, at 2, FTC Matter No. P221200 (July 9, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf. Accordingly, the Interim Report is "tentative or interlocutory in nature," and not final agency action. *Sisseton-Wahpeton Oyate*, 888 F.3d at 915.

Second, and independently, the Interim Report is not final agency action because it neither determines legal rights and obligations nor compels legal consequences. Put simply, the Interim Report neither requires ESI to take any action nor forbids any conduct. *Id.* (final agency action "may either compel affirmative action or prohibit otherwise lawful action"). To the contrary, the Interim Report makes clear that it is intended only to "share initial evidence about . . . practices that urgently warrant further scrutiny and *potential* regulation." Interim Report at 71 (emphasis added). Such tentative identification of potential future regulation does not determine legal rights, and is therefore not final agency action. *Sierra Club*, 446 F.3d at 813 (memorandum of agreement not final agency action where it "merely identified sites that *might* justify building levees").

ESI alleges that the Interim Report "has real-world legal consequences" because it "in effect announces that various business practices of PBMs . . . are unlawful." Compl. ¶ 118, ECF No. 1. But an agency does not determine legal rights or obligations "merely by expressing its view of the law." *Sisseton-Wahpeton Oyate*, 888 F.3d at 915; *see also Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 946 (D.C. Cir. 2012) (no final agency action where an "agency merely expresses its view of what the law requires of a party, even if that view is adverse to the party") (citation omitted). That is because the Interim Report's view of the law "has force only to the extent the agency can persuade a court to the same conclusion." *AT&T Co. v. E.E.O.C.*, 270 F.3d 973, 976 (D.C. Cir. 2001).

ESI also alleges that the Interim Report "has already given rise to enforcement actions and litigation," Compl. ¶ 119, but concedes that those actions have been brought by independent third-parties. And "harms caused by agency decisions are not legal consequences" for purposes of establishing final agency action "if they stem from independent actions taken by third parties." *Parsons v. U.S. Dep't of Just.*, 878 F.3d 162, 168 (6th Cir. 2017). That rule holds true even if the defendant agency may itself legally sanction the regulated party through a process beginning with the challenged agency action. *See Peoples Nat'l Bank v. Off. of Comptroller of Currency of U.S.*, 362 F.3d 333, 337 (5th Cir. 2004) (an agency action that "does not of itself adversely affect complainant but only affects his rights adversely on the contingency of future administrative action" is not final); *Veldhoen v. U.S. Coast Guard*, 35 F.3d 222, 225 (5th Cir. 1994) ("[T[he plaintiff must await resolution of the agency's inquiry and challenge the final agency decision . . . . An attack on the authority of an agency to conduct an investigation does not obviate the final agency action requirement.").

The Fourth Circuit's decision in *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852 (4th Cir. 2002), is illustrative. There, like here, the plaintiff challenged an agency report that had "no direct regulatory effect on plaintiffs" in that it neither compelled nor forbade any particular action on its part. *Id.* at 858. The district court concluded that the report was final agency action because it

"carried indirect regulatory effects" in that it encouraged other government entities to regulate the plaintiff. *Id.* The Fourth Circuit reversed, explaining that agency action "producing only coercive pressures on third parties" is not final agency action because it does not itself determine legal rights or obligations. *Id.* at 859. And that remained true even if "the Report's persuasive value may lead private groups to impose . . . restrictions" detrimental to plaintiffs or even increase their vulnerability to liability because "no statutory scheme triggers potential civil or criminal penalties for failing to adhere to the Report's recommendations." *Id.* at 861. So, too, here.

II. ESI's defamation claim (Count I) should be dismissed.

A. This Court lacks subject-matter jurisdiction over a state-law defamation claim brought against federal defendants.

This Court lacks subject-matter jurisdiction over ESI's defamation claim because Defendants have not waived sovereign immunity from state-law tort claims. *Hart v. United States*, 630 F.3d 1085, 1088 (8th Cir. 2011) ("Where the United States has not waived sovereign immunity . . . the district court lacks subject matter jurisdiction to hear the case."). Congress determined that the sole vehicle by which tort claims may be asserted against federal officials is the Federal Tort Claims Act ("FTCA"). But the FTCA excludes ESI's state-law defamation claim from its waiver of sovereign immunity three times over: the FTCA expressly forbids suits sounding in defamation; it expressly forbids suits arising from an official's exercise of discretion, such as the release of information pertaining to the Commission's investigation; and it does not authorize declaratory or injunctive relief. Accordingly, this Court should dismiss ESI's state-law defamation claim for lack of subject-matter jurisdiction.

1. "The basic rule of federal sovereign immunity is that the United States cannot be sued at all without the consent of Congress." *Block v. North Dakota*, 461 U.S. 273, 287 (1983). A waiver "must be unequivocally expressed in statutory text, and will not be implied." *Lane v. Pena*, 518 U.S. 187, 192 (1996) (internal citation omitted). "Moreover, a waiver of the Government's sovereign immunity will be strictly construed, in terms of its scope, in favor of the sovereign." *Id.* And Congress must

"provide[] 'clear and unambiguous' authorization" to permit state law to regulate federal activities, *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 180 (1988) (citation omitted).

"The FTCA serves as a limited waiver of sovereign immunity, opening the door to state-law liability claims against the federal government for harm caused by government employees." *Buckler v. United States*, 919 F.3d 1038, 1044 (8th Cir. 2019). The FTCA's limited waiver of sovereign immunity is the sole vehicle by which state-law tort claims may be brought against Federal defendants, which are otherwise immune from such suits—it provides "the exclusive remedy for most claims against Government employees arising out of their official conduct." *Hui v. Castaneda*, 559 U.S. 799, 806 (2010). And "[s]ince the United States can be sued only to the extent that it has waived its immunity, due regard must be given to the exceptions." *United States v. Orleans*, 425 U.S. 807, 814 (1976). Accordingly, the FTCA does not provide a waiver of sovereign immunity if ESI's state-law defamation claim falls within one of the FTCA's exceptions. *Hart*, 630 F.3d at 1088 ("The United States is . . . immune if an exception applies.").

2. The FTCA's waiver of sovereign immunity excludes ESI's state-law defamation claim for three independent reasons, any one of which forecloses subject-matter jurisdiction here. For one, the FTCA excludes intentional torts, including defamation, from its waiver of sovereign immunity. 28 U.S.C. § 2680(h) (excluding "[a]ny claim arising out of . . . libel [and] slander"); *see also Simpkins v. D.C. Gov't*, 108 F.3d 366, 371 (D.C. Cir. 1997) ("[F]ederal employees acting within the scope of their duties are immune from common law actions for libel and slander."). And ESI cannot evade this exception to the waiver of sovereign immunity by renaming its claim as "defamation": under Missouri law, "libel and slander have evolved to the point where modern law combines them as the generic tort of defamation." *Nazeri v. Missouri Valley Coll.*, 860 S.W.2d 303, 308 (Mo. 1993); *see also Moessmer v. United States*, 760 F.2d 236, 237-38 (8th Cir. 1985) ("If the gravamen of his complaint is that the [government

defendant] communicated defamatory material . . . then his claim falls within the libel and slander exception to the FTCA.").

Moreover, the discretionary-function exception withholds the FTCA's waiver of sovereign immunity for ESI's defamation claim. Pursuant to that exception, the United States and its officials "expressly retain[] immunity in cases involving a 'discretionary function or duty.'" *Mound v. United States*, --- F. 4th ----, 2023 WL 3911505, at *1 (8th Cir. June 9, 2023). "To determine whether [a] case involves 'a discretionary function or duty,'" courts consider: (1) whether "the conduct at issue 'involve[d] an element of judgment or choice'"; and (2) whether "the conduct at issue was 'susceptible to policy analysis'" because the exception "is meant to 'prevent judicial second-guessing of ... decisions grounded in social, economic, and political policy.'" *Id.* Both conditions are met here. The Commission's release of nonconfidential information under 15 U.S.C. § 46(f) indisputably involves an element of judgment or choice because, as explained *supra* pp. 6-9, the sole standard by which that release is assessed is whether it is "in the public interest." *See Metter v. United States*, 785 F.3d 1227, 1231 (8th Cir. 2015) (conduct involved agency choice where "nothing . . . prescribes 'a specific, mandatory duty'"). And whether release of information is "in the public interest" is the precise type of policy analysis the exception intends to shield. *United States v. Gaubert*, 499 U.S. 315, 323 (1991) ("[T]he actions of Government agents involving the necessary element of choice and grounded in the social, economic, or political goals of the statute and regulations are protected.").

Finally, ESI seeks declaratory and injunctive relief for its tort claim, Compl. Prayer for Relief ¶ ii, which the FTCA does not permit. *See* 28 U.S.C. § 1346(b); *Fiorito v. United States*, No. 22-cv-2879, 2023 WL 5000217, at *1 (D. Minn. Aug. 4, 2023) ("Fiorito is also incorrect in arguing that declaratory relief is available under the FTCA."); *Est. of Trentadue ex rel. Aguilar v. United States*, 397 F.3d 840, 863 (10th Cir. 2005) ("the district court lacks subject matter jurisdiction under the FTCA to provide

injunctive and declaratory relief"). Thus, the FTCA's waiver of sovereign immunity is unavailable for ESI's state-law defamation claim.

3. Nor may ESI rely on the APA's waiver of sovereign immunity to assert a state-law defamation claim against federal officials. To be sure, Section 702 of the APA "waives federal sovereign immunity," *Preferred Risk Mut. Ins. Co. v. United States*, 86 F.3d 789, 792 (8th Cir. 1996), and some courts have held that waiver is not limited to cases brought under the APA, *see, e.g.*, *Trudeau v. FTC*, 456 F.3d 178, 186 (D.C. Cir. 2006). But the APA does not "confer[] authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought." 5 U.S.C. § 702. For state-law tort claims, the FTCA is such a statute. And it both expressly (as to tort suits sounding in defamation and tort suits implicating discretionary functions) and impliedly (as to tort suits seeking declaratory relief) forbids the relief ESI seeks here. Accordingly, the APA does not waive sovereign immunity for ESI's defamation claim here.

The Supreme Court's decision in *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209 (2012), guides this analysis. In that case, the Supreme Court considered a hypothetical quiet title claim involving Indian lands brought under the APA's waiver of sovereign immunity notwithstanding the Quiet Title Act's waiver of sovereign immunity for quiet title claims "*except when* they involve Indian lands (which this hypothetical suit does)." *Id.* at 216. The Court explained that the APA's waiver of sovereign immunity would not encompass such a suit because the Quiet Title Act's more specific waiver excludes claims involving Indian lands. *Id.* Thus, "[w]hen Congress has dealt in particularity with a claim and [has] intended a specified remedy'—including its exceptions—to be exclusive, that is the end of the matter; the APA does not undo the judgment." *Id.* (quoting *Block*, 461 U.S. at 286 n. 22). The same is true here: the carve-outs from the FTCA's more specific waiver of sovereign immunity trump the APA's general waiver of sovereign immunity for claims that, like ESI's state-law defamation claim, fall squarely within the FTCA's carve-outs. *See El-*

Shifa Pharm. Indus. Co. v. United States, 607 F.3d 836, 854 (D.C. Cir. 2010) (en banc) (Kavanaugh, J., concurring in the judgment) (explaining that while the FTCA "expressly borrow[s] (or permit[s]) state tort causes of action against the United States in certain carefully defined circumstances . . . . the APA does not borrow state law or permit state law to be used as a basis for seeking injunctive or declaratory relief against the United States"); *Cambranis v. Blinken*, 994 F.3d 457, 466 (5th Cir. 2021) (holding that, because "Congress intended § 1503(a) to be the exclusive remedy," "the 'any other statute' proviso of § 702 maintains the United States' sovereign immunity"); *Sierra Club v. Wheeler*, 956 F.3d 612, 619 (D.C. Cir. 2020) (similar).

In any event, the APA cannot provide the requisite waiver of sovereign immunity here because, "[u]nder the APA, sovereign immunity is waived if the claimant challenges a 'final agency action.'" *Batsche*, 875 F.3d at 1177; *see also Gallo Cattle Co. v. USDA*, 159 F.3d 1194, 1198 (9th Cir. 1998) ("the APA's waiver of sovereign immunity contains several limitations" including requirement that agency action either be made reviewable by statute or constitute "final agency action"). As explained *supra* pp. 9-12, ESI does not challenge a final agency action. Similarly, the APA specifies that the entire chapter, including the waiver of sovereign immunity, "applies . . . except to the extent that—agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). As explained *supra* pp. 6-9, that is also the case here.

B. The Supremacy Clause bars ESI's state-law defamation claim.

The Supremacy Clause also stands as a fundamental and independent barrier to ESI's state-law claim. Federal law is "the supreme Law of the Land," U.S. Const. art. VI, cl. 2, and it has been firmly established for two centuries that states have no power "to retard, impede, burden, or in any manner control, the operations of the constitutional laws enacted by congress to carry into execution the powers vested in the general government." *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 436

(1819); *see also, e.g.*, *Mayo v. United States*, 319 U.S. 441, 445 (1943) ("activities of the Federal Government are free from regulation by any state").

Thus, even where Congress has waived sovereign immunity, "[a]n absence of immunity does not result in liability" where the substantive law invoked does not "reach the federal entity." *U.S. Postal Serv. v. Flamingo Indus. (USA) Ltd.*, 540 U.S. 736, 744 (2004). Here, the Missouri common-law defamation claim cannot reach the federal Defendants because the Supremacy Clause "prohibit[s] States from interfering with or controlling the operations of the Federal Government," including by "regulat[ing] the United States directly." *United States v. Washington*, 596 U.S. 832, 838 (2022) (citation omitted). In other words, "Supremacy Clause immunity protects federal officers, acting within their federal authority, from liability under state law," whether by "prosecution or private suit." *Texas v. Kleinert*, 855 F.3d 305, 313-14 (5th Cir. 2017). And that prohibition extends to "even the most unquestionable and most universally applicable of state laws." *Johnson v. Maryland*, 254 U.S. 51, 56-57 (1920); *see, e.g.*, *Ohio v. Thomas*, 173 U.S. 276, 283 (1899) ("[W]hen discharging [their] duties under federal authority pursuant to and by virtue of valid federal laws, [federal officers] are not subject to . . . liability under the laws of the state in which their duties are performed."); *Arizona v. California*, 283 U.S. 423, 451 (1931) ("The United States may perform its functions without conforming to the police regulations of a state."). Accordingly, so long as the conduct about which ESI complains is authorized by federal law (it is, *supra* pp. 6-9), ESI cannot obtain relief under state law.[5]

C. In any event, ESI fails to state a defamation claim under Missouri law.

Even if this Court has jurisdiction over ESI's defamation claim, it should dismiss the first count because ESI has failed to state a claim for defamation. Under Missouri law, a plaintiff must

[5] This understanding of the federal government's Supremacy Clause immunity also follows from principles of federal preemption, which underscore that a state may not interpose its tort laws "as an obstacle to the accomplishment and execution" of federal agents' enforcement of federal law. *Arizona v. United States*, 567 U.S. 387, 399, 406 (2012).

allege "(1) publication (2) of a defamatory statement (3) that identifies the plaintiff, (4) that is false, (5) that is published with the requisite degree of fault, and (6) that damages the plaintiff's reputation." *Turntine v. Peterson*, 959 F.3d 873, 882 (8th Cir. 2020). ESI alleges that two statements are defamatory: that PBMs are "inflating drug costs" and that PBMs "profit at the expense of patients by inflating drug costs." Compl. ¶¶ 131-138. The former is taken from the title of the Interim Report and repeated in the press release; the latter appears only in the press release. Neither statement could support a defamation claim because neither is false in context. *Cockram v. Genesco, Inc.*, 680 F.3d 1046, 1051 (8th Cir. 2012) (under Missouri law, "if a statement is essentially true, . . . the statement is not actionable.").

First, the Interim Report establishes that PBM business practices can contribute to increased drug prices. *See* Interim Report at 39-40. As evidence, the Interim Report compared for two widely used generic cancer drugs the "gross reimbursement rates paid by Big 3 PBM-managed payers to their PBM's affiliated pharmacies with" the National Average Drug Acquisition Cost ("NADAC")—"a common measure of pharmacy acquisition costs of drugs based on amounts reported to the Centers for Medicare & Medicaid Services"—and "with the rates paid to unaffiliated pharmacies." Interim Report at 38-40.[6] That comparison demonstrated that pharmacies affiliated with the Big 3 PBMs received "high gross reimbursement rates from the health plans they manage for the two case study drugs, often roughly 20- to 40-times higher than NADAC." *Id.* at 41. And the Interim Report explained that those inflated rates impacted consumers: "the average cost sharing for [Medicare] Part D members on" one of the two drugs "was higher than NADAC in 2021, the last period for which PBM respondents produced full-year data." *Id.* at 43-44.[7] "In other words, these patients paid more out of pocket, on average, than the estimated acquisition cost of their drugs." *Id.* at 44.

[6] The "Big 3" PBMs are CVS Caremark, ESI, and OptumRx. Interim Report at 5.

[7] Medicare Part D is the Medicare prescription drug benefit, which helps Medicare beneficiaries pay for prescription drugs. *See* 42 U.S. Code § 1395w–102.

ESI does not allege that the data concerning these two drugs is false, and instead argues that the Interim Report should have conducted a different analysis "across the basket of all drugs." Compl. ¶ 106. But the Interim Report does not purport to have conducted a complete analysis of all products—to the contrary, it expressly discloses that its "findings are necessarily limited to the two case study drugs." Interim Report at 40. In other words, ESI's claim arises from its own gloss on the Interim Report's qualified conclusions, and ESI never disputes the accuracy of either the Interim Report's actual conclusions or the data disclosed as the basis for those conclusions. ESI cannot state a claim by relying on its own version of unstated conclusions or a "subjective interpretation of data" that the Interim Report does not offer. *See Smith v. Humane Soc'y of United States*, 519 S.W.3d 789, 802 (Mo. 2017) (en banc) (statements that "reflect a subjective interpretation of data" are not actionable); *cf. ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 498 (2d Cir. 2013) ("[T]o the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising . . ."); *Pacira BioSciences, Inc. v. Am. Soc'y of Anesthesiologists, Inc.*, 63 F.4th 240, 248 (3d Cir. 2023) ("critiques about the Articles' data and methodology may be the basis of future scholarly debate, but they do not form the basis for trade libel").[8]

Second, the statement that PBMs "profit at the expense of patients by inflating drug costs" is not actionable. As an initial matter, assessing whether statements are actionable requires that the words "be considered in context." *Sterling v. Rust Commc'ns*, 113 S.W.3d 279, 282 (Mo. Ct. App. 2003). And in the context of the Interim Report, Commission Staff make clear the statements are based on specific case studies, the accuracy of which ESI does not dispute. And even then, the Interim Report

[8] ESI faults the Commission Staff generally for relying on public sources. Compl. ¶ 10. But the Interim Report cites PBM data for information regarding the two test-case drugs. *See* Interim Report at 41 n.200.

qualifies on the first page of the executive summary the conclusion that ESI challenges, explaining that it describes how PBMs "*may* be profiting by inflating drug costs." Interim Report at 1 (emphasis added). ESI does not and cannot argue that conditional statement, in context, is false.

In any event, ESI does not dispute the substantive basis for the Interim Report's conclusion that PBMs may profit at patients' expense by inflating drug costs. As explained above, the Interim Report examines two case study drugs and connects PBMs' profits from those drugs to "[t]he high levels of dispensing revenue in excess of NADAC that PBM-affiliated pharmacies are receiving," because "the high reimbursement rates paid to PBM-affiliated pharmacies translate into substantial revenue gains for those pharmacies." *Id.* at 44-45. By having the commercial health plans and Medicare Part D prescription drug plans that they manage pay their affiliated pharmacies rates grossly in excess of drug acquisition costs as measured by NADAC, PBMs can increase profits. Interim Report at 45-47. ESI does not claim that any of these statements are false.

Accordingly, the Interim Report "details how prescription drug middleman profit at the expense of patients," as stated in the Press Release. That the Interim Report contains such detail independently forecloses liability under Missouri law for an accompanying statement that summarizes those conclusions, even if ESI disagrees with the conclusions in the underlying report. *See Nigro v. St. Joseph Med. Ctr.*, 371 S.W.3d 808, 819 (Mo. Ct. App. 2012) ("[W]ith respect to Davis's reporting what the committees found or did, her statements will be deemed true even if the committees erroneously made their findings."); *Rice v. Hodapp*, 919 S.W.2d 240, 244 (Mo. 1996) (en banc) ("[T]he statement was true in the sense that State Farm management, after an investigation, believed Rice had committed sexual harassment.").

III. ESI fails to state a due process claim (Count II).

A. ESI fails to allege that the Commission's release of the Interim Report deprives ESI of its life, liberty, or property.

The Fifth Amendment prohibits the government from depriving any person of "life, liberty, or property, without due process of law." U.S. Const. amend. V. Accordingly, the requirement for an unbiased adjudicative body applies only where required to protect some life, liberty, or property interest. As the Eighth Circuit has explained, "[t]he process of providing an unbiased and impartial tribunal does not exist in a vacuum, it exists to afford due process when due process is required to protect a liberty [or property] interest." *Jenner v. Nikolas*, 828 F.3d 713, 717 (8th Cir. 2016); *see also Marshall v. Jerrico, Inc.*, 446 U.S. 238, 242 (1980) ("The Due Process Clause entitles a person to an impartial and disinterested tribunal . . . . to guarantee that life, liberty, or property will not be taken on the basis of an erroneous or distorted conception of the facts or the law.").

ESI has not pleaded that the Commission's release of the Interim Report threatens any such interest. For reasons similar to those establishing that the Interim Report is not final agency action, *supra* pp. 9-11, the release of that report does not deprive ESI of any liberty or property interest. The Interim Report does not impose legal liability. It neither compels ESI to take any action nor requires that ESI cease any action it is currently undertaking. In short, the Interim Report does not regulate ESI—to the contrary, it makes clear that it is intended only to "share initial evidence about" practices "that urgently warrant . . . *potential* regulation." Interim Report at 71 (emphasis added).

Nor can ESI salvage its claim by alleging that the Interim Report "damages [ESI's] reputation." Compl. ¶ 121. The Supreme Court has squarely held that even "serious[] … harm[]" to a plaintiff's "reputation" does not "deprive him of any 'liberty' or 'property' interests protected by the Due Process Clause." *Paul v. Davis*, 424 U.S. 693, 712 (1976); *see also Neal v. Fields*, 429 F.3d 1165, 1167 (8th Cir. 2005) ("Injury to reputation alone is not a liberty interest protected" by the Due Process Clause). Nor do ESI's allegations that the Interim Report has resulted in third-party lawsuits and state investigations

against ESI, Compl. ¶ 8, establish a liberty or property interest. The Due Process Clause is "a limitation on the [government's] power to act . . . . It forbids the [government] itself to deprive individuals of life, liberty, or property without 'due process of law,'" but does not render the government liable for actions of independent third parties that deprive a plaintiff of a liberty or property interest. *DeShaney v. Winnebago Cnty. Dep't of Soc. Servs.*, 489 U.S. 189, 195 (1989).[9]

Thus, because ESI fails to show that the Commission's release of the Interim Report violated any liberty or property interest, ESI fails to state a due process claim. *Dobrovolny v. Moore*, 126 F.3d 1111, 1113 (8th Cir. 1997) ("[W]here no such interest exists, there can be no due process violation.").

B. Even if due process protections were applicable, ESI fails to state a claim that those protections were violated.

ESI also fails to state a due process claim because ESI does not allege a conflict of interest, but mere bias. Compl. ¶¶ 69-80. Administrative officials exercising investigatory functions are not, however, required to be "neutral and detached." *Marshall*, 446 U.S. at 248; *id.* ("The rigid requirements of *Tumey* and *Ward*, designed for officials performing judicial or quasi-judicial functions, are not applicable to those acting in a prosecutorial or plaintiff-like capacity," which "are necessarily permitted to be zealous in their enforcement of the law."); *cf. Baker v. Kempthorne*, No. 4:08-cv-077, 2009 WL 1444719, at *1 (D.N.D. May 20, 2009) ("A prosecutor is required to refrain from participating in an investigation . . . 'if such participation may result in a personal, financial, or political conflict of interest, or the appearance thereof.' . . . 'There is no rule that prosecutors are required to be neutral and

[9] ESI's allegation that it "spent millions of dollars" to respond to the Commission, Compl. ¶ 15, does not create a property or liberty interest that attaches to ESI's claim concerning the *publication* or *contents* of the Interim Report. ESI does not (and could not) allege that the Commission's Section 6(b) PBM investigation is itself a violation of due process in light of the indisputable authority that Congress granted the Commission to conduct such investigations. 15 U.S.C. § 46(b). And even Commissioner Holyoak's dissenting statement (which ESI cites repeatedly, *e.g.*, Compl ¶ 11) concluded that she "would encourage the Commission to continue its investigation." Commissioner Holyoak, FTC, *Dissenting Statement in the Matter of the Pharmacy Benefit Managers Report*, at 7 n.30, FTC Matter No. P221200 (July 9, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Holyoak-Statement-Pharmacy-Benefit-Managers-Report.pdf.

detached.'") (citations omitted). And when the Commission under Section 6(f) releases information gathered during a study under Section 6(b), the Commission acts in an investigatory, rather than adjudicative, capacity because the Commission is making broad recommendations about the state of an industry, not resolving disputes between distinct parties. *Cf. Forrester v. White*, 484 U.S. 219, 227 (1988) ("paradigmatic judicial acts involve[] . . . resolving disputes between parties who have invoked the jurisdiction of a court"). Accordingly, the neutrality requirements that ESI invokes do not apply and ESI has failed to state a claim.

In any event, even if the Commission's Section 6(b) and 6(f) functions were properly classified as adjudicatory, ESI must "bear the heavy burden of establishing that [an] administrative hearing was unfair." *S. Dakota v. U.S. Dep't of Interior*, 775 F. Supp. 2d 1129, 1137 (D.S.D. 2011); *see also United States ex rel. De Luca v. O'Rourke*, 213 F.2d 759, 765 (8th Cir. 1954) (plaintiff must make a "substantial showing of bias to disqualify a hearing officer in administrative proceedings"). That is because a party claiming bias on the part of an administrative body must overcome "a presumption of honesty and integrity in those serving as adjudicators." *In re Morgan*, 573 F.3d 615, 624 (8th Cir. 2009) (quoting *Withrow v. Larkin*, 421 U.S. 35, 47 (1975)). Thus, "[i]n the absence of clear evidence to the contrary, courts . . . presume that public officers have discharged their official duties properly." *State of S. Dakota v. U.S. Dep't of Interior*, 401 F. Supp. 2d 1000, 1011 (D.S.D. 2005), *aff'd*, 487 F.3d 548 (8th Cir. 2007). None of ESI's three allegations of bias clears this high bar:

First, ESI alleges that the Commission's prior statements recognizing the competitive benefits of PBMs evince a bias on the part of the current Commission, which voted to withdraw those prior statements. Compl. ¶¶ 69-74. But far from signaling that it had already decided to discard those prior statements and reports, the Commission made clear that the study "will enable the Commission to consider the extent to which prior conclusions about the PBM industry remain valid." Withdrawal Statement at 1. The Commission's statement therefore does not indicate prejudgment, but merely

cautions regulated parties against relying on certain statements and reports because the "Commission is currently engaged in a major study of the PBM industry" in response to "substantial changes" that "have taken place" in the industry "over the last two decades." *Id.* In any event, agencies are free to change their minds so long as they explain why they are departing from their prior conclusion. *Cf. FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514-15 (2009) (if there "are good reasons for the new policy," an agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better").

Second, ESI alleges that release of the Interim Report over dissenting and concurring statements evinces bias. Compl. ¶¶ 75-77. But mere disagreement does not render the majority's opinions biased—indeed, some of the Commission's reports on which ESI relies were issued over dissenting statements. *See, e.g.*, Compl. ¶ 71 (citing FTC, *Statement Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.*, FTC File No. 111-0210 (Apr. 2, 2012)); Commissioner Julie Brill, *Dissenting Statement Concerning the Proposed Acquisition of Medco Health Solutions Inc. by Express Scripts, Inc.*, FTC File No. 110-0210 (Apr. 2, 2012), https://www.ftc.gov/sites/default/files/documents/public_statements/dissenting-statement-commissioner-julie-brill/120402medcobrillstatement.pdf. And neither Commissioner Holyoak's dissenting statement nor the concurring statement of Commissioner Ferguson even suggest, much less establish, that the Interim Report's conclusions were the result of bias. *See* Andrew N. Ferguson, Commissioner, FTC, *Concurring Statement Regarding the Pharmacy Benefit Managers Interim Staff Report*, at 4, FTC Matter No. P221200 (July 9, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf ("I cannot think of a good reason to deny to the public and Congress the staff's understanding of those markets more than two years after we issued the June 2022 orders.").

Third, ESI alleges that Chair Khan's statements evince bias and prejudgment. Compl. ¶¶ 78-80. As an initial matter, none of the examples that ESI offers have anything to do with the Commission decision's decision to release an interim report. Regardless, none of the statements ESI offers as evidence clears the high bar necessary to state a claim:

As an initial matter, Chair Khan's statements made in a Politico article that she published as a law student cannot establish bias as a matter of law—"comments by adjudicators outside their official duties are not enough, standing alone, to require disqualification." *Zen Magnets, LLC v. Consumer Prod. Safety Comm'n*, 968 F.3d 1156, 1175 (10th Cir. 2020). In any event, those statements expressed her view in April 2016 that "PBMs joined to pharmacies tend to steer plan members away from independent entities and to their own affiliates." Lina Khan, *How to Reboot the FTC*, POLITICO (April 13, 2016), https://www.politico.com/agenda/story/2016/04/ftc-antitrust-economy-monopolies-000090/. Contrary to ESI's misleading paraphrase of her article, she noted that a conflict of interest "*can* . . . sap PBMs of the incentive to bargain for lower reimbursement rates and keep drug prices high." *Id.* (emphasis added). The mere recognition of that possibility is a far cry from prejudgment. But even if it were a fully formed view, "no basis for disqualification arises from the fact . . . that a member of an administrative agency enters a proceeding with advance views on important economic matters in issue." *Skelly Oil Co. v. Fed. Power Comm'n*, 375 F.2d 6, 18 (10th Cir. 1967), *rev'd in part on unrelated grounds sub nom. In re Permian Basin Area Rate Cases*, 390 U.S. 747 (1968); *see also United States v. Morgan*, 313 U.S. 409, 421 (1941) (concluding that the Secretary of Agriculture's expression of "strong views" on an issue did not require disqualification from participating in related proceedings).

Nor do Chair Khan's statements to the National Community Pharmacists Association in June 2022, *see* Compl. ¶ 78, reflect prejudgment about whether ESI and other PBMs are engaged in unlawful business practices. Rather, Chair Khan merely noted the importance of PBMs, which "play a critical role that have enormous consequences on people's day-to-day lives." Lina M. Khan, Chair, FTC, *How*

Pharmacy Benefit Managers Impact Drug Prices, Communities, and Patients, Remarks at the American Economic Liberties Project and the National Community Pharmacists Association (June 22, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Remarks-Lina-Khan-Economic-Liberties-National-Community-Pharmacists-Association.pdf.

Likewise, Chair Khan's statements before a Subcommittee of the Senate Judiciary Committee in September 2022 explained only that the Commission had authorized a study to assess the operations of PBMs. Lina M. Khan, Chair, FTC, *Oversight of the Enforcement of the Antitrust Laws*, Prepared Statement of the Federal Trade Commission Before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights (Sept. 20, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P210100SenateAntitrustTestimony09202022.pdf. ESI may dispute whether its operations are "opaque," but that dispute does not constitute clear evidence that Chair Khan had already decided those operations are unlawful. *See Zen Magnets*, 968 F.3d at 1172 ("measured" statement insufficient evidence of bias); *FTC v. Cement Inst.*, 333 U.S. 683, 701 (1948) (rejecting due process challenge where party failed to show that "the minds of [the FTC's] members were irrevocably closed" to its arguments). And merely citing the PBM investigation cannot establish bias because it is clear from the context that she was simply citing it to illustrate the importance of the Commission's work. *See Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 80 (10th Cir. 1972) (no bias where "it is clear that Commissioner Jones was discussing the complaint and was doing so in an effort to illustrate a point"). ESI stretches even further by attempting to impute statements (and clothing choices) of individuals speaking at the same conference to Chair Khan. Compl. ¶ 78. The only alleged statements from her—that "Chair Khan pledged to crack down on illegal practices and to investigate the causes of high drug prices," *id.*—do not approach prejudgment.

Similarly, Chair Khan's May 4, 2023 statements that PBMs "are sitting right in the middle and controlling the types of practices that independent pharmacies are facing," were prefaced with the

qualifying statement that the Commission was "looking closely at the ways in which potentially unlawful practices may be contributing to high drug prices" and "so we're looking very closely at that [insulin] entire supply chain and identifying . . . what are the actors that may be acting in unlawful business practices here." *See* Economic Liberties, *2023 Anti-Monopoly Summit*, YOUTUBE (May 4, 2023), https://www.youtube.com/watch?v=_MUdBWApI9k&t=3928s at 1:22-23. In context, then, Chair Khan was clear that the Commission had not yet reached any conclusions.

Chair Khan's remarks at a White House event on PBMs also made clear that she had not resolved the outcome of the Commission's investigation, explaining the Commission was "more determined than ever to understand how PBM's *could* be causing problems in the drug supply chain." Lina M. Khan, Chair, FTC, *Remarks at the White House Roundtable on PBMs*, at 2 (Mar. 4, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/2024.03.04-chair-khan-remarks-at-the-white-house-roundtable-on-pbms.pdf (emphasis added). And, while ESI misleadingly quotes Chair Khan as if she were espousing conclusions about the study, the remarks show that she was instead relaying "stories we hear from patients and healthcare workers." *Id.* at 1. Chair Khan's February 14, 2024, statements similarly conveyed that the Commission has "heard concerns about how PBMs *may* unfairly discriminate" and that "the rebates that PBMs demand *may* function as kickbacks." Lina M. Khan, Chair, FTC, *Remarks at the American Medical Association National Advocacy Conference*, at 4 (Feb. 14, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/remarks-chair-khan-ama-nationaladvocacy-conference.pdf (emphasis added). Accordingly, none of these statements overcome the presumption that Chair Khan has "discharged [her] official duties properly." *S. Dakota*, 401 F. Supp. 2d at 1011.

IV. Supreme Court precedent bars ESI's Article II claim (Count V).

A. ESI's claim that the Commission's structure violates Article II of the Constitution should be dismissed because it is contrary to binding Supreme Court precedent. In *Humphrey's Executor v. United States*, 295 U.S. 602 (1935), the Supreme Court upheld the constitutionality of the

Commissioners' removal restrictions. Then, as now, the President could remove FTC commissioners for only "inefficiency, neglect of duty, or malfeasance in office." 15 U.S.C. § 41. The Court "found it 'plain' that the Constitution did not give the President 'illimitable power of removal' over the officers of independent agencies," and held that the "'coercive influence' of the removal power would 'threaten the independence of the commission.'" *Morrison v. Olson*, 487 U.S. 654, 687-88 (1988) (quoting *Humphrey's Ex'r*, 295 U.S. at 630) (alterations omitted). And after *Humphrey's Executor*, "removal restrictions have been generally regarded as lawful for so-called 'independent regulatory agencies,' such as the Federal Trade Commission." *Morrison*, 487 U.S. at 724-25 (Scalia, J., dissenting).

Accordingly, *Humphrey's Executor* "remain[s] binding precedent" on the constitutionality of the Commission's removal restrictions "until [the Supreme Court] see[s] fit to reconsider [it], regardless of whether subsequent cases have raised doubts about [its] continuing vitality." *Bosse v. Oklahoma*, 580 U.S. 1, 3 (2016) (per curiam) (quoting *Hohn v. United States*, 524 U.S. 236, 252-53 (1998)). And that remains true even if recent decisions called into question (without overturning) *Humphrey's Executor*: As the Supreme Court instructs, if its "precedent . . . has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the [lower court] should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions." *Rodriguez de Quijas v. Shearson/Am. Exp., Inc.*, 490 U.S. 477, 484 (1989).

That instruction controls here because, in recent cases addressing the President's removal power, the Supreme Court has expressly declined to reconsider *Humphrey's Executor*. In *Seila Law LLC v. CFPB*, for instance, the Court emphasized that it was not "revisit[ing] [its] prior decisions allowing certain limitations on the President's removal power." 591 U.S. 197, 204 (2020); *id.* at 215 (explaining that "*Free Enterprise Fund* left in place two exceptions to the President's unrestricted removal power," including *Humphrey's Executor*); *see also Collins v. Yellen*, 594 U.S. 220, 250-51 (2021) (similar). If anything, *Seila Law* reaffirmed *Humphrey's Executor*'s holding as to the Commission by explaining that the

structure of the CFPB—which was run by a single Director—would be constitutional if it were "convert[ed] . . . into a multimember agency," like the Commission. 591 U.S. at 237. Similarly, in *Free Enterprise Fund v. Public Company Accounting Oversight Board*, the Supreme Court invalidated removal restrictions for certain inferior officers who could be removed only by SEC commissioners, but noted that the constitutional defect could be remedied by making the inferior officers removable at will by the commissioners while leaving the SEC commissioners removable for inefficiency, neglect of duty or malfeasance in office—the same protection applicable to FTC commissioners. 561 U.S. 477, 496 (2010).

For these reasons, every court to address the issue to date has held that, "although the FTC's powers may have changed since *Humphrey's Executor* was decided," whether *Humphrey's Executor* is "no longer binding is for the Supreme Court, not [this court], to answer." *Illumina, Inc. v. FTC*, 88 F.4th 1036, 1047 (5th Cir. 2023); *see also Meta Platforms, Inc. v. FTC*, No. 24-5054, 2024 WL 1549732, at *2 (D.C. Cir. Mar. 29, 2024); *FTC v. Am. Nat. Cellular, Inc.*, 810 F.2d 1511, 1514 (9th Cir. 1987); *FTC v. Kochava Inc.*, 671 F. Supp. 3d 1161, 1178-79 (D. Idaho 2023); *FTC v. Roomster Corp.*, 654 F. Supp. 3d 244, 260 (S.D.N.Y. 2023); *H&R Block Inc. v. Himes*, No. 24-00198-CV-W-BP, 2024 WL 3742310, at *1 (W.D. Mo. Aug. 1, 2024); *see also In re Aiken Cnty.*, 645 F.3d 428, 446 (D.C. Cir. 2011) (Kavanaugh, J., concurring) ("*Humphrey's Executor* is an entrenched Supreme Court precedent, protected by stare decisis."). This Court should do the same.

B. Even if the Commissioners' removal protections were unconstitutional (they are not), ESI's claim should still be dismissed because the challenged removal protections had no effect on the Interim Report that ESI challenges. In *Collins v. Yellen*, the Supreme Court emphasized that relief from an unconstitutional removal protection requires a connection between the challenged administrative action and the asserted constitutional defect. 594 U.S. at 257-58 ("Although the statute unconstitutionally limited the President's authority to remove the confirmed Directors, there was no

constitutional defect in the statutorily prescribed method of appointment to that office. As a result, there is no reason to regard any of the actions taken by the FHFA . . . as void."). And the Court made clear that unlawful removal restrictions do not render invalid all actions taken by the executive official protected by those restrictions: "[s]ettled precedent . . . confirms that the unlawfulness of the removal provision does not strip" executive officials "of the power to undertake the other responsibilities of [their] office." *Id.* at 258 n.23. Accordingly, "a party challenging agency action must show not only that the removal restriction transgresses the Constitution's separation of powers but also that the unconstitutional provision caused (or would cause) them harm." *Bhatti v. FHFA*, 97 F.4th 556, 559 (8th Cir. 2024) (quotation omitted); *see also Leachco, Inc. v. Consumer Prod. Safety Comm'n*, 103 F.4th 748, 756 (10th Cir. 2024).

Here, ESI alleges no connection between the challenged removal protections and the Interim Report. ESI has not shown, for example, that the President has sought to remove the current Commissioners because of the Interim Report or even that he disagrees with the Interim Report's conclusions. Nor does ESI allege that the current Commissioners were not properly nominated for and appointed to their positions. This failure independently dooms ESI's claim because the party alleging a removal violation may obtain relief "only when the President's inability to fire an agency head *affected the complained-of decision*." *Collins*, 594 U.S. at 274 (Kagan, J., concurring) (emphasis added); *see also Bhatti*, 97 F.4th at 559. The proper course is therefore dismissal under Rule 12(b)(6). *Commonwealth Prop. Advocates, L.L.C. v. Mortg. Elec. Registration Sys., Inc.*, 680 F.3d 1194, 1202 (10th Cir. 2011) ("Dismissal is appropriate if the law simply affords no relief."); *Target Training*, 1 F. Supp. 3d at 936 (same).

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion to dismiss.

Dated: December 16, 2024

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

CHRISTOPHER HALL
Assistant Branch Director

/s/ Alexander W. Resar

ALEXANDER W. RESAR (N.Y. Bar 5636337)
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L ST. N.W.
Washington, DC 20005
Tel: (202) 616-8188
alexander.w.resar@usdoj.gov

Counsel for Defendants